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APPLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	NO. CONFIRMATION NO.		
09/927,757	09/927,757 08/09/2001		Todd K. Whitehurst	AB-124U1	5963		
23845	7590	06/14/2004		EXAM	EXAMINER		
		NICS CORPORATI	BOCKELM	BOCKELMAN, MARK			
25129 RYE VALENCIA	,			ART UNIT	PAPER NUMBER		
	<b>-,</b>			3762	3		
				DATE MAILED: 06/14/200	<b>14</b>		

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application	No.	Applicant(s)	
0.55	09/927,757		WHITEHURST ET AL.	
Office Action Summary	Examiner		Art Unit	
• * *	Mark W Boo		3762	
The MAILING DATE of this commun Period for Reply	ication appears on the c	over sheet with the	correspondence address	••
A SHORTENED STATUTORY PERIOD F THE MAILING DATE OF THIS COMMUNI  - Extensions of time may be available under the provisions after SIX (6) MONTHS from the mailing date of this comm  - If the period for reply specified above, the maximum st  - Failure to reply within the set or extended period for reply Any reply received by the Office later than three months a earned patent term adjustment. See 37 CFR 1.704(b).	ICATION. of 37 CFR 1.136(a). In no event, nunication. 0) days, a reply within the statutor atutory period will apply and will e will, by statute, cause the applica	however, may a reply be ti ry minimum of thirty (30) da xpire SIX (6) MONTHS fror tion to become ABANDON	mely filed  ys will be considered timely.  In the mailing date of this communication (35 U.S.C. § 133).	ation.
Status				
1) Responsive to communication(s) file	ed on .			
	2b)⊠ This action is nor	ı-final.		
3) Since this application is in condition	· —		rosecution as to the merit	s is
closed in accordance with the practi				
Disposition of Claims				
4) ⊠ Claim(s) <u>1-48</u> is/are pending in the a 4a) Of the above claim(s) is/a  5) □ Claim(s) is/are allowed.  6) ⊠ Claim(s) <u>1-13,15-17, 19-24,31, 33-</u> 7) ⊠ Claim(s) <u>14,18,25-30,32,36 and 43-</u> 8) □ Claim(s) are subject to restrice	are withdrawn from cons 35 and 37-42 is/are rejocated to.	ected.		
Application Papers				
9)☐ The specification is objected to by th	e Examiner.			
10) The drawing(s) filed on is/are		objected to by the	Examiner.	1
Applicant may not request that any obje	ction to the drawing(s) be	held in abeyance. So	ee 37 CFR 1.85(a).	
Replacement drawing sheet(s) including 11) The oath or declaration is objected to				
,_	by the Examiner. Note	the attached Onic	e Action of format 10-102	
Priority under 35 U.S.C. § 119			) (I) (G	
12) Acknowledgment is made of a claim a) All b) Some * c) None of:  1. Certified copies of the priority 2. Certified copies of the priority 3. Copies of the certified copies application from the Internation * See the attached detailed Office action	documents have been documents have been of the priority documen onal Bureau (PCT Rule	received. received in Applica ts have been receiv 17.2(a)).	tion No /ed in this National Stage	;
Attachment(s)		)	(DTO 442)	
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (F</li> </ol>	4 °TO-948)	) Interview Summar Paper No(s)/Mail [	y (₽10-413) Date	
3) Information Disclosure Statement(s) (PTO-1449 or Paper No(s)/Mail Date 2.	· PTO/SB/08) 5		Patent Application (PTO-152)	

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#### **DETAILED ACTION**

# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 recites the limitation "the sensed condition" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 13, 15, 17, 24, 31, 33-35, 39, 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury".

Creasy teaches the implantation of a Finetech-Brindley stimulation system with positioning of the electrodes intradurally wherein the electrode extends through the dura through a grommet see page 507 column 2 first paragraph. Although not explicitly stated it is apparent that the turning on and off of the device constitutes "at least one pulse" which would inherently travel acroos the dura through the grommet protion.

Penile erection was observed (Page 511). As noted by applicant, the procedure is usually accompanied by posterior rhizotomy which suggest that sometimes it is not.

Thus the limitations of claim 13 wherein the posterior roots are left in tact are met.

Claims 13, 15-17, 21, 24, 31, 33-35, 39 and 42 are ejected under 35 U.S.C. 103(a) as being unpatentable over Tai et al "Penile Erection Produced by Microstimulation of the Sacral Spinal cord of the Cat" in further view of Cameron et al "Micromodular Implants to provide Electrical Stimulation of Paralyzed Muscles and Limbs, orCreasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury, or Meloy et al USPN 6,169,924. Tai teaches the intradura placement of electrodes into the ventral root of the s1-s3 segments to effect penile erection. No dorsal roots are damaged. The signals are carried across the dura to provide stimulation. Applicant differs in reciting that the stimulator is implanted in the patient. It was well know, as evidenced by Creasy Meloy and Cameron to place the stimulator

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itself within the patients body. To have provided an implanted stimulator in the Tai et al method for log term study and to reduce risks of infection would have been obvious.

Claims 19-20, 22-23, 34-35, 37-38, 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury", or alternatively Tai et al "Penile Erection Produced by Microstimulation of the Sacral Spinal cord of the Cat" in further view of Cameron et al "Micromodular Implants to provide Electrical Stimulation of Paralyzed Muscles and Limbs, or Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury, or Meloy et al USPN 6,169,924. as applied above, either in view of Lue et al "Electrostimulation and Penile Erection of Meloy et al US 61169,924

Applicant differs in reciting various stimulation areas outside the S1-s4 area of the base references and including the T1-L3 segments. Lue et al and Meloy et al both teach such area to be likely segments for success in treating erectile dysfunction and therefore would be obvious alternative stimulation areas to the base references for achieving the desired results.

Claims 1-6, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury" or Tai et al "Penile Erection Produced by Microstimulation of the Sacral Spinal cord of the Cat" either in further view of Cameron et al "Micromodular Implants to provide Electrical Stimulation of Paralyzed Muscles and Limbs. Creasy and Tai each teach the

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implantation of electrodes and generating and delivering pulses to nerves into various spinal segments to effect penile erection. Providing power to the system is inherent. Applicant differs in reciting that the implant is sized so as to be deliverable through a hypodermic tube. Cameron et al teaches a microstimulator that is sized to be inserted through a hypodermic tube which includes all the necessary power and electronics to deliver pulses to nerves. To have made the implanted stimulator of Crease a size that can be delivered through a hypodermic tube or to have used such a device in the Tai et al disclosure would have been obvious in light of the fact that the Cameron device is utilized for treating sacral anterior nerve roots for sexual function, the same results desired by Tai and Creasey. To have provide a sensor for detecting the transmission of data and or power and/or for detecting when a transdermal controller is position thereby would have been obvious

Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury" or

Tai et al "Penile Erection Produced by Microstimulation of the Sacral Spinal cord of the

Cat" either in further view of Cameron et al "Micromodular Implants to provide Electrical

Stimulation of Paralyzed Muscles and Limbs as applied to claims 16, 9-11 above, and

further in view Meloy et al USPN 6,169,924 or Lue et al "Electrostimulation and Penile

Erection". Applicant differs in reciting various spinal segments T10-T-12 and L1-L4 as

spinal segments to effect penile erection, such segments being taught by Lue et al

rendering the selection of spinal segment obvious.

#### Allowable Subject Matter

Claims, 14,18,25-30, 32, 36, 43-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 12 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**MWB** 

May 31, 2004